



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/816,252

04/02/2004

David Walter Wright

115624

8511

25944 7590 05/28/2008

OLIFF & BERRIDGE, PLC

P.O. BOX 320850

ALEXANDRIA, VA 22320-4850

EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/816,252	Applicant(s) WRIGHT ET AL.	
	Examiner NATHAN A. BOWERS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 31-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 56-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>041305, 040204</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-30 and 56-64 in the reply filed on 07 March 2008 is acknowledged. The traversal is on the ground that there is no serious burden on the examiner to examine all the claims. This is not found persuasive because each group is drawn to a different classification and requires separate searching and consideration.

The requirement is still deemed proper and is therefore made FINAL.

Claims 31-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07 March 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 1) Claim 63 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 recites the limitation "the sensor" in line 4. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2) Claims 1-4 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Gremel (US 6918887).

With respect to claim 1, Gremel discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 4:30) having a top, bottom and side walls. A first opening (Figure 4:44) allows gas and liquid to enter the chamber, a second opening (Figure 4:34) is configured to allow gas to exit the chamber, and a third opening (Figure 4:48) is configured to allow liquid to exit the chamber. This is taught in column 2, line 46 to column 3, line 11. Figure 4 shows that the second opening is located in a middle portion of the top of the chamber, and that the third opening is located in a middle portion of the bottom of the chamber.

With respect to claims 2-4, Gremel discloses the apparatus in claim 1 wherein the chamber is located within a housing. The outer shell of the chamber walls is considered to represent a housing such that the first, second and third openings cause fluid to move through the chamber and housing.

With respect to claim 12, Gremel discloses the apparatus in claim 3 wherein tubing is connectable to each of the plurality of openings. This is apparent from Figure 3.

3) Claims 1-4, 10-12, 18, 56-58, 63 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahy (US 5586438).

With respect to claims 1 and 56, Fahy discloses an apparatus for separating gas from a liquid path comprising a chamber (Figure 1:111) having a top, bottom and side walls. A first opening connected to an inlet line (Figure 1:120) allows gas and liquid to enter the chamber, second openings (Figure 1:116 and Figure 1:122) are configured to allow gas to exit the chamber, and a third opening connected to an outlet line (Figure 1:110) is configured to allow liquid to exit the chamber. This is disclosed in column 5, lines 27-49 and in column 6, line 33 to column 7, line 122. Figure 1 shows that the second openings are located in a middle portion of the top of the chamber, and that the third opening is located in a middle portion of the bottom of the chamber. Fahy further teaches that the chamber is in communication with an organ or tissue transporter (Figure 1:11).

With respect to claim 2-4, Fahy discloses the apparatus in claim 1 wherein the chamber is located within a housing. The outer shell of the organ transporter encompasses the chamber such that the first, second and third openings cause fluid to move through the chamber and housing.

With respect to claims 10, 57, 58 and 64, Fahy discloses the apparatus in claims 2 and 56 wherein the housing is in communication with the organ transporter (Figure 1:11). The housing and tubing are connectable to a frame (Figure 6:256) capable of supporting the housing, organ transporter and tubing.

With respect to claim 11, Fahy discloses the apparatus in claim 2 wherein at least part of the housing is transparent. This is disclosed in column 3, line 64 to column 4, line 6.

With respect to claims 12 and 18, Fahy discloses the apparatus in claim 3 wherein tubing is connectable to each of the plurality of openings. This is apparent from the Figures.

With respect to claim 63, Fahy discloses the apparatus in claim 58 wherein a pumping system is used to move liquids from the chamber to the organ transporter. Fahy teaches in column 6, line 66 to column 7, line 6 that roller pumps are used to transfer fluid to and from the organ transporter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4) Claims 1-12, 18-30 and 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 20040029266).

With respect to claims 1 and 56, Barbera-Guillem discloses a tissue transporter (Figure 1:100) comprising a chamber (Figure 1:170) that includes a top, bottom and side surfaces. A first opening (Figure 33:300) is configured to allow liquids and gases to enter the chamber, and a second opening is provided in communication with a tubing (Figure 33:498) to remove gas from the chamber. This is disclosed in paragraphs

[0262] and [0263]. From Figure 33, it appears that the second opening is provided in a middle portion of the top of the chamber. If the second opening is not provided in a middle portion of the top of the chamber, it would have been obvious to position the second opening at this location. The selection of an exact area to situate a gas outlet at the top of a container is merely a design choice arrived at through a simple rearrangement of parts. Although Barbera-Guillem does not provide a Figure in which a third opening is provided, it would have been obvious to provide additional openings through which liquids could be removed. Paragraph [0058] states that at least one inlet/outlet is provided, thereby strongly implying that it would have been obvious to include a third opening similar to the first opening capable of removing liquids from the chamber. It would have been to ensure that this third opening is situated at the middle portion of the bottom of the chamber if it was determined that this location resulted in the most effective removal of fluids from the chamber.

With respect to claims 2-9, Barbera-Guillem discloses the apparatus in claim 1 wherein an outer housing is used to enclose the inner chamber. The outer housing includes openings (Figure 1:320 and Figure 1:220) that correspond to the inner first, second and third openings positioned within the chamber. This is more clearly illustrated in Figure 33. Tubing (Figure 33:500 and Figure 33:490) is used to connect each outer housing opening with a corresponding inner chamber opening. From Figure 1, it is apparent that openings located on the housing are situated upon a common plane of the same sidewall. Although Barbera-Guillem shows that the openings are

located near a top of the same side surface, it would have been obvious to locate each opening on the sidewall according to any predetermined arrangement.

With respect to claims 10, 57 and 58, Barbera-Guillem discloses the apparatus in claims 2 and 56 wherein the housing is in communication with the inner chamber which functions as a tissue transporter.

With respect to claim 11, Barbera-Guillem discloses the apparatus in claim 2 wherein at least part of the housing is transparent. This is disclosed in paragraph [0057].

With respect to claims 12 and 18, Barbera-Guillem discloses the apparatus in claim 3 wherein tubing is connectable to each of the plurality of openings. This is apparent from Figure 33.

With respect to claims 19-30, Barbera-Guillem discloses the apparatus in claim 4 wherein entrance and exit channels (Figure 33:500 and Figure 33:496) are used to connect each housing opening with a respective chamber opening. Figure 33 indicates that the first housing opening is at a top portion of the housing and that the first chamber opening is at a bottom portion of the chamber. Figures 32 and 33 show that portions of the entrance and exit channels are curved, and that some portions of the entrance and exit channels are approximately horizontal and others approximately vertical. It would have been obvious to construct the entrance and exit channels according to any desirable shape or size that resulted in the most effective fluid transfer to and from the chamber.

5) Claims 13-17 and 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5586438) as applied to claims 12 and 58, and further in view of Sadri (US 5494822).

Fahy discloses the apparatus set forth in claims 12 and 58 as set forth in the 35 U.S.C. 102 rejection above, however does not expressly state that a sensor is provided for detecting gas moving through the first and/or third housing openings.

Sadri discloses a device for transporting and maintaining an organ that comprises a chamber (Figure 1:25) for holding the organ, a fluid supply line (Figure 1:13) and an oxygenator (Figure 1:6). This is disclosed in column 10, line 34 to column 11, line 6. Column 6, lines 11-20 further state that a bubble trap is provided between the oxygenator and the perfused organ. Sensors (Figure 1:14) monitor gas levels of fluid moving from the bubble trap to the organ chamber. Column 11, lines 50-58 state that the flow rate of perfusate flowing into the organ is altered in response to gas level characteristics measured in the fluid. Column 7, lines 40-60 indicate that the operation of the pumping mechanisms and valves regulating the fluid system are controlled in response to measurements made by the gas sensors. Although Sadri does not specifically disclose the use of a ultrasonic gas sensor, ultrasonic gas sensors are considered to be well known in the art. It would have been obvious to use any known sensor in the apparatus of Sadri.

Fahy and Sadri are analogous art because they are from the same field of endeavor regarding organ and tissue transporting means.

At the time of the invention, it would have been obvious to equip the apparatus of Fahy with a gas monitoring probe capable of interacting with a control system designed to regulate fluid flow to and from the organ in response to detected gas levels. Sadri teaches that it is important to maintain appropriate gas levels within an organ perfusion device in order to sustain conditions suitable for tissue growth. Automated systems are beneficial because they are accurate, cost effective and reliable.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797